

Stage 3/2015 Edition Health IT Certification Criteria Proposed Rules Overview May 11, 2015







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STAGE 3 MEANINGFUL USE PROPOSED RULE OVERVIEW



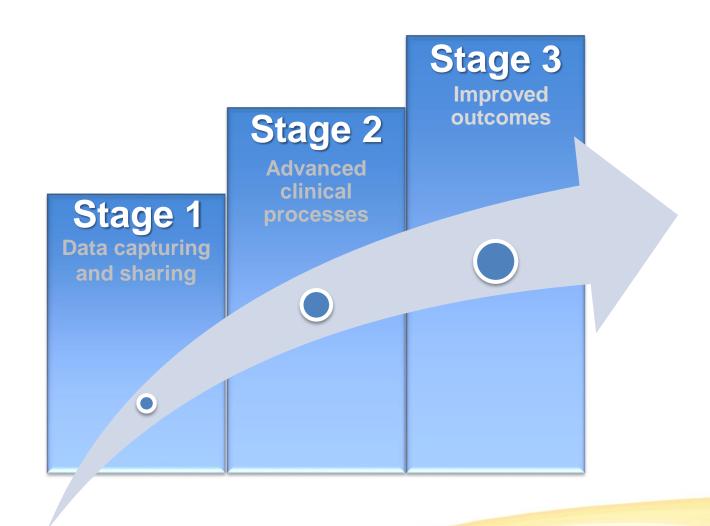
Learning Objectives

1 Understand approach for Stage 3

Explain Stage 3 proposed requirements

Differentiate between previous requirements and Stage 3







Stage 3 NPRM Requirements



3

Goals of Proposed Provisions

Provide a flexible, clear framework to simplify the meaningful use program and reduce provider burden

Ensure future sustainability of Medicare and Medicaid EHR Incentive Programs

Advance the use of health IT to promote health information exchange and improved outcomes for patients



Stage 3 NPRM Streamlines Programs

Streamlining

 Synchronizing on single stage and single reporting period



Stage 3 NPRM Streamlines Programs

Streamlining

- Reducing burden by removing objectives that are:
 - Redundant paper based versions of now electronic functions
 - Duplicative of other more advanced measures using same certified EHR technology function
 - Topped out and have reached high performance



Stage 3 NPRM Streamlines Programs

Streamlining

8 advanced use objectives



Stage 3 NPRM Improves Outcomes

Stage 3 NPRM focuses on objectives which support advanced use of EHR technology and quality improvement

Health information exchange objectives improve outcomes by:

- Ensuring providers caring for same patient are sharing info with one another
- Providing patients with easy access to health info
- Fostering data collection in sharable format across multiple health care organizations
- Supporting learning health system through sharing of common clinical dataset and expanding types of registries to which hospitals and providers can report



Stage 3 NPRM Provides Flexibility

The Stage 3 proposed rule makes the meaningful use program more flexible:

- Have option to report on Stage 3 criteria in 2017
- Required to report on Stage 3 beginning in 2018 regardless of prior participation/stage of meaningful use



Stage 3 NPRM Provides Flexibility

The Stage 3 proposed rule makes the meaningful use program more flexible:

- Simplifying meaningful use objectives and measures and allowing flexible measures for:
 - health information exchange
 - consumer engagement
 - public health reporting
- Providing enhanced flexibility and options for public health reporting



Stage 3 Requirements, Objectives & Measures



Reporting Period

- » Full calendar year reporting period beginning in 2017
- » CQM reporting in coordination with quality reporting programs



Stage 3 Proposed Objectives

- 1. Protect Electronic Health Information
- 2. Electronic Prescribing (eRx)
- 3. Clinical Decision Support
- 4. Computerized Provider Order Entry (CPOE)
- 5. Patient Electronic Access to Health Information
- 6. Coordination of Care through Patient Engagement
- 7. Health Information Exchange
- 8. Public Health Reporting



Retained Stage 2 objectives with modifications



Objective	Measure(s)
Protect Electronic Health Information	Conduct or review a security risk analysis including addressing the encryption/security of data stored in CEHRT, and implement security updates as necessary and correct identified security deficiencies as part of the EP's, EH's, or CAH's risk management process.
Electronic Prescribing (eRx)	EP Measure: More than 80% of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. EH/CAH Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.
Clinical Decision Support	 EPs, EHs, and CAHs must satisfy both measures in order to meet the objective: Measure 1: Implement at least 5 CDS interventions tied to clinical quality measures or key high-priority health conditions. Measure 2: Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.
Computerized Provider Order Entry (CPOE)	More than 80% of medication, 60% of laboratory, and 60% of "diagnostic imaging" orders are recorded using CPOE. EPs, eligible hospital, or CAH must meet all 3 measures.



Objectives with expanded scope:

- 1. Patient Electronic Access to Health Information
- 2. Coordination of Care through Patient Engagement
- 3. Health Information Exchange
- 4. Public Health Reporting



Objective

Measure(s)

Patient Electronic Access to Health Information

EPs/EHs/CAHs must satisfy both measures in order to meet the objective.

Measure 1

 More than 80% of all unique patients seen by the EP or discharged from the hospital during the EHR reporting period are provided access to new information within 24 hours of its availability to the EP/EH/CAH, subject to the provider's discretion to withhold certain information.

Measure 2

 Use clinically relevant information from CEHRT to identify patientspecific educational resources and provide electronic access to those materials to 35% of patients.



Objective

Measure(s)

Coordination of Care through Patient Engagement

EPs/EHs/CAHs must attest to 3 measures, but meet 2 out of 3 thresholds:

Measure 1

 More than 25% of all unique patients (or authorized representatives) under the care of the EP/EH/CAH during the EHR reporting period (1) view, (2) download, or (3) transmit to a third party their health information. Or enable API and meet Measure 1 of Patient Electronic Access Objective.

Measure 2

 EP/EH/CAHs communicate with patients electronically through secure messaging for 35% of patients encountered during the reporting period. In patient-to-provider communication, provider must respond to patient to receive credit under this objective. "Communicate" means when a provider sends a message to patients OR when a patient sends a message to the provider and the provider responds.

Measure 3

 EP/EH/CAH must use health information received electronically from a non-physician source for 15% of patients encountered by EP/EH/CAH in the reporting period and must use health information received from a patient or from the patient's caregiver for 5% of patients encountered by the EP/EH/CAH in the reporting period.



Objective

Measure(s)

Health Information Exchange

EPs/EHs/CAHs must attest to 3 measures, but meet 2 out of 3 thresholds:

Measure 1

The EP/EH/CAH that transitions or refers their patient to another setting
of care or to another provider of care creates and exchanges an
electronic summary of care record for 50% of such transitions of care
and referrals. The electronic summary of care must be sent in
accordance with the standards for transitions of care set by ONC.

Measure 2

 The EP/EH/CAH must receive, request or query for a patient's electronic summary of care record that has been created by another setting of care or provider of care for 40% of all new patient encounters during the reporting period. The electronic summary of care must be accessed in accordance with the standards for transitions of care set by ONC.

Measure 3

 Clinical Information Reconciliation (CIR) – Providers perform clinical information reconciliation for more than 80% (percent will be the same as Measure 1) of transitions of care in which the patient is transitioned into the care of the EP/EH/CAH. Provider may choose to reconcile 2 out of 3 of the following: meds, problems, and allergies.



Objective	Measure(s)
Public Health Reporting	Providers must report data on an ongoing basis to established public health registries. Registry options: Immunization, syndromic surveillance, ELR, specialized (PDMP, cancer, etc.)
	• EP Objective: Report 3 measures from #1-5
	EH/CAHs Objective: Report 4 measures from #1-6
	Measure 1- Immunization Registry Reporting
	 Measure 2- Syndromic Surveillance Reporting
	Measure 3- Case Reporting
	 Measure 4- Public Health Registry Reporting*
	 Measure 5- Clinical Data Registry Reporting**
	Measure 6- Electronic Reportable Laboratory Results
	*Providers may choose to report to more than one public health registry to meet the number of measures.
	*Providers may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.



Modifications to Meaningful Use in 2015-2017 NPRM



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Goals of Proposed Provisions

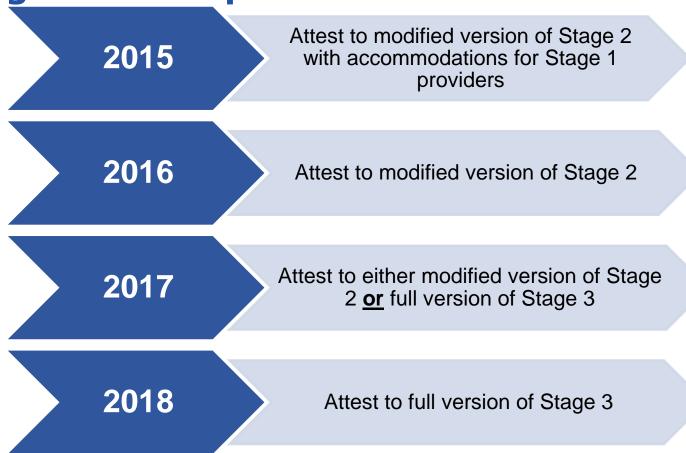
Align with Stage 3 proposed rule to achieve overall goals of programs

Synchronize reporting period objectives and measures to reduce burden

Continue to support advanced use of health IT to improve outcomes for patients



Changes to Participation Timeline





Alignment of Meaningful Use NPRMs

The Stage 1 and 2 Modification NPRM reconciles measures to align criteria for 2015 to 2017 with Stage 3 to:

- Prepare providers to report Stage 3 criteria in 2018
- Reduce provider burden and create a single set of sustainable objectives that promote best practices for patients
- Enable providers to focus on objectives which support advanced use of health IT, such as:
 - health information exchange
 - consumer engagement
 - public health reporting



Submitting Comments

- 1. Electronically:
- You may submit electronic comments on this regulation to: http://www.regulations.gov/#!submitComment;D=CMS-2015-0033-0002
- Follow the "Submit a comment" instructions.
- 2. By regular mail
- 3. By express or overnight mail
- 4. By hand or courier



CMS Help Desks

» EHR Information Center Help Desk

- (888) 734-6433 / TTY: (888) 734-6563
- Hours of operation: Monday-Friday 8:30 a.m. 4:30 p.m. in all time zones (except on Federal holidays)

» NPPES Help Desk

- Visit https://nppes.cms.hhs.gov/NPPES/Welcome.do
- (800) 465-3203 TTY (800) 692-2326

» PECOS Help Desk

- Visit https://pecos.cms.hhs.gov/
- (866)484-8049 / TTY (866)523-4759

» Identification & Access Management System (I&A) Help Desk

- PECOS External User Services (EUS) Help Desk Phone: 1-866-484-8049
- TTY 1-866-523-4759
- E-mail: <u>EUSSupport@cgi.com</u>



2015 Edition Proposed Rule Modifications to the ONC Health IT Certification Program and the 2015 Edition Health IT Certification Criteria

Elise Sweeney Anthony, Deputy Director, Office of Policy Michael L. Lipinski, Director, Division of Federal Policy and Regulatory Affairs



2015 Edition Health IT Goals



INTEROPERABILITY

ACCESS

USER/MARKET RELIABILITY

SUPPORTING THE CARE CONTINUUM

INTEROPERABILITY





- New and updated vocabulary and content standards for the structured recording and exchange of health information (including the 2015 Base EHR Definition and the Common Clinical Data Set)
- Transitions of Care
 - ☐ Both versions of the Consolidated CDA (Release 1.1 and Release 2.0) + Edge Protocol
 - □ Rigorously testing C-CDA creation, templates, vocabulary codes; and XDM processing
 - ☐ Patient matching data with constraints

INTEROPERABILITY



2015 Base EHR Definition

Focuses on the functionalities that all users of certified Health IT should minimally possess consistent with the HITECH Act requirements.

Base EHR Capabilities	Certification Criteria	
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics, Problem List, Medication List, Medication Allergy List, Smoking, and Implantable Device List	
Capacity to provide clinical decision support	Clinical Decision Support	
Capacity to support physician order entry	Computerized Provider Order Entry	
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures (CQMs)- record and export	
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care, Data Portability, Application Access to Common Clinical Data Set, and ["Direct" or "Direct, Edge Protocol, and XDR/XDM"]	

INTEROPERABILITY

ACCESS



The Common Clinical Data Set includes key health data that should be exchanged using specified vocabulary standards and code sets as applicable

Patient name	Lab tests	
Sex	Lab values/results	
Date of birth	Vital signs	
Race	Procedures	
Ethnicity	Care team members	
Preferred language	Immunizations	
Problems	Unique device identifiers for implantable devices	
Smoking Status	Assessment and plan of treatment	
Medications	Goals	
Medication allergies	Health concerns	

ONC Interoperability Roadmap Goal

2015-2017

Send,
receive, find
and use a
common
clinical data
set to
improve
health and
health care
quality.

ACCESS



 The 2015 Edition also proposes that Common Clinical Data Set be available for additional use cases, including data portability, VDT and API.



Data Portability



View, download, and transmit to 3rd Party



Respond to application programming interface (API) requests for data

USER/MARKET RELIABILITY



Privacy and Security



Patient Safety



Surveillance and Certification
 Maintenance



Transparency



SUPPORTING THE CARE CONTINUUM



- Current: Prior editions were adopted with a specific focus on the EHR Incentive Programs
- Proposed: A more accessible ONC Health IT Certification Program supportive of:
 - ☐ Diverse health IT systems, including but not limited to EHR technology ("Health IT Module" instead of "EHR Module")
 - Remember that there is no "Complete EHR" certification to the 2015 Edition or future editions
 - ☐ Health IT across the care continuum, including long-term and post acute care settings
- "Available/Optional" certification criteria, including supporting health disparities:
 - ☐ Exchange of sensitive health information (data segmentation for privacy)
 - ☐ Record of social, psychological, and behavioral data
 - ☐ Laboratory exchange
 - ☐ Care plan

SUPPORTING THE CARE CONTINUUM



A number of programs currently use or are proposing to use the ONC Health IT Certification Program. Here are a few:

- Physician Self-Referral Law exception and Anti-kickback
 Statute safe harbor for certain EHR donations
- CMS chronic care management services
- Department of Defense Healthcare Management System Modernization Program
- The Joint Commission for participation as ORYX vendor eCQMs for hospitals



Certification to the 2015 Edition Use Cases (MU & Beyond)

Certification Program Requirements				
Criteria proposed as always required for 2015 Edition certification (n=2)	Criteria proposed as conditional for 2015 Edition certification depending on capabilities in scope (n= 10)	Proposed 2015 Edition criteria pointed to by CMS for MU 3 & to implement statute (Base EHR definition) (n=37)		Available proposed 2015 Edition criteria for certification (n=19)
Quality Management System - (g)(4)	Authentication, Access Control, Authorization- (d)(1)	CPOE Medications (a)(1)	Patient-specific Education Resources - (a)(17)	Vital Signs, BMI, and Growth Charts - (a)(6)
Accessibility-Centered Design-(g)(8)	Auditable Events and Tamper-resistance- (d)(2)	CPOE Laboratory (a)(2)	Patient Health Information Capture – (a)(19)	Image results - (a)(13)
	Audit Report(s) - (d)(3)	CPOE Diagnostic Imaging (a)(3)	Implantable Device List - (a)(20)	Patient List Creation - (a)(16)
	Amendments - (d)(4)	Drug-drug, Drug-allergy Interaction Checks for CPOE – (a)(4)	Transitions of Care – (b)(1)	eMAR- (a)(18)
	Automatic Access Time-out - (d)(5)	Demographics (a)(5)	Clinical Information Reconciliation and Incorporation – (b)(2)	Social, Psychological, and Behavioral Data - (a)(21)
	Emergency Access-(d)(6)	Problem List – (a)(7)	E-Rx - (b)(3)	Decision Support – knowledge artifact - (a)(22)
	End-User Device Encryption-(d)(7)	Medication list – (a)(8)	Data Portability – (b)(6)	Decision Support – service - (a)(23)
	Integrity - (d)(8)	Medication Allergy List – (a)(9)	CQM — record and export - (c)(1)	Incorporate Laboratory Tests and Values/Results – (b)(4)
	Safety Enhanced Design - (g)(3)	CDS — (a)(10)	CQM – import and calculate – (c)(2)	Transmission of Laboratory Test Reports – (b)(5)
	Consolidated CDA Creation Performance – (g)(6)	Drug-formulary and Preferred Drug List Checks –(a)(11)	CQM – report (c)(3)	DS4P – send (b)(7)
Green = new to the 2015 Edition		Smoking Status - (a)(12)	VDT - (e)(1)	DS4P – receive (b)(8)
	a in the "available"	Family Health History (a)(14); or Family Health History – Pedigree (a)(15)	Secure messaging - (e)(2)	Care Plan - (b)(9)
column previously adopted in an		Transmission to Immunization Registries (f)(1)	Transmission to PHA – case reporting (f)(5)	CQM filter - (c)(4)
edition to support MU1/MU2 Red Font = "unchanged" criteria		Transmission to PHA – syndromic surveillance (f)(2)	Transmission to PHA – antimicrobial use and resistance reporting (f)(6)	Accounting of Disclosures – (d)(9)
(eligible for gap ce	rtification)		(f)(7)	Accessibility technology compatibility (g)(5)
Blue Font = "minimally revised" criteria		Transmission to Cancer Registries (f)(4)		SOAP Transport and Security Specification and
		Application Access to Common Clinical Data Set – (g)(7)		Healthcare Provider Directory – query request (h)(4)
Black Font/Gray Background = "revised" criteria		- III 300 (B/(r)	Protocol, and XDR/XDM (h)(2)	Healthcare Provider Directory – query response (h)(5)
				Electronic Submission of Medical Documentation—(i)(1)

Certification Responsibilities for Health IT Developers

certification responsibilities for freathfre bevelopers			
IF you seek product certification to the following:	THEN your product will <u>always</u> need to be certified to:	AND will also need to be certified to:	
Any clinical criterion in 45 CFR 170.315(a)	 The privacy & security (P&S) criteria at § 170.315(d)(1)-(d)(7) Quality management system (QMS) at § 170.315(g)(4) Accessibility-centered design (ACD) at § 170.315(g)(8) 	Safety-enhanced design (SED) at § 170.315(g)(3) if you seek certification to any one of the following criteria: § 170.315(a)(1)-(10), (18), (20), (22), and (23)	
Any care coordination criterion in 45 CFR 170.315(b)	 The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5) - (d)(8) QMS at § 170.315(g)(4) and ACD at (g)(8) 	SED at § 170.315(g)(3) if you seek certification to any one of the following criteria: • § 170.315(b)(2)-(b)(4) Consolidated CDA performance at § 170.315(g)(6) if you seek certification to any one of the following criteria:	

6) § 170.315(b)(1), (2), (6), (7), and (9)

ing The P&S criteria at § 170.315(d)(1)-(d)(3) N/A QMS at § 170.315(g)(4) and ACD at (g)(8) N/A QMS at § 170.315(g)(4)

Any clinical quality measures criterion in 45 CFR 170.315(c) • Any privacy and security ACD at § 170.315(g)(8)

criterion in 45 CFR 170.315(d) • Any patient engagement The P&S criteria at $\S 170.315(d)(1)-(d)(3)$, (d)(5), and (d)(7)Consolidated CDA performance at § 170.315(g)(6) criterion in 45 CFR 170.315(e) • QMS at § 170.315(g)(4) and ACD at (g)(8) if you seek certification to § 170.315(e)(1) The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(7) N/A

Any public health criterion in 45 CFR 170.315(f) QMS at § 170.315(g)(4) and ACD at (g)(8)

45 CFR 170.315(g)(1) or (2) N/A QMS at § 170.315(g)(4)

45 CFR 170.315(g)(7) QMS at § 170.315(g)(4) and ACD at (g)(8) Consolidated CDA performance at § 170.315(g)(6) Any transport methods and The P&S criteria at § 170.315(d)(1)-(d)(3) Transitions of care at § 170.315(b)(1) if you seek other protocols criterion in QMS at § 170.315(g)(4) and ACD at (g)(8) certification to § 170.315(h)(1)

The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5)-(d)(8)

QMS at § 170.315(g)(4) and ACD at (g)(8)

Any administrative criterion

in 45 CFR 170.315(i)

45 CFR 170.315(h)

Consolidated CDA performance at § 170.315(g)(6)

if you seek certification to § 170.315(i)(1)

Proposed EHR Incentive Programs Stage 3 Meaningful Use Objectives



- Objective 1: Protect Patient Health Information
- Objective 2: Electronic Prescribing
- Objective 3: Clinical Decision Support
- Objective 4: Computerized Provider Order Entry
- Objective 5: Patient Electronic Access to Health Information
- Objective 6: Coordination of Care through Patient Engagement
- Objective 7: Health Information Exchange
- Objective 8: Public Health and Clinical Data Registry Reporting

Certified Health IT Module(s) to Support the EHR Incentive Programs Stage 3

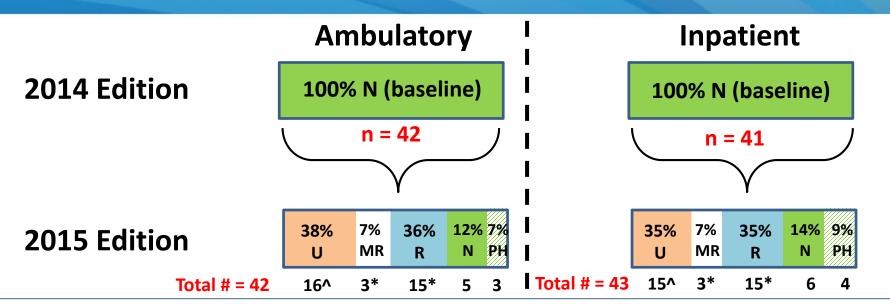


(Objective 5 only) (Objectives 5 & 6) (Objective 6 (Objective 7) (Objective 8) Certification View, Download, & Patient-specific only) Transitions of Care; and "Public Health" Criteria to **Education** Transmit to 3rd Party; **Clinical Information** (EP: choose 3 of 6: Secure Support and API Access to CCDS Reconciliation & Incorp EH/CAH: choose 4 of 6 Resources Messaging Meeting **Specific** (Objective 3) (Objective 2) (Objective 4) **Objectives** e-Prescribing; and Clinical Decision Support; and **Computerized Provider Order Entry Drug-formulary Checks Drug-drug, Drug-allergy Interaction Checks CEHRT Family Health History** Import and Calculate; and **Patient Health Information Capture** Definition (and supports Objective 6) (choose 1 of 2) **Report CQMs** Requirements **CEHRT** Definition Meaningful Use Measurement Capabilities/Certification Criteria Requirements CEHRT/ Base EHR **Base EHR Capabilities/Certification Criteria** Definition Requirements Conditional Certification **Privacy & Security** Safety-enhanced Design **CCDA Creation Performance** Requirements Mandatory **Quality Management System Accessibility-centered Design** Certification Requirements

What is Minimally Required for Stage 3?

2014 Edition vs. Proposed 2015 Edition





Bottom Line

- 45% of criteria are unchanged or minimally revised for the ambulatory setting.
- 42% of criteria are unchanged or minimally revised for the inpatient setting.
- Only need to do ~60% of the proposed 2015 Edition criteria to participate in Stage 3.
- The total minimum number of criteria needed to participate in Stage 3 remains the same for EPs and almost the same for EHs/CAHs as compared to Stage 2.
 - Note: This analysis does not account for potential exclusions

U = Unchanged criteria MR = Minimally revised criteria

R = Revised criteria

N = New criteria

PH = Public health criteria (new and revised. EPs choose 3 of 6 measures and EHs/CAHs choose 4 of 6 measures.

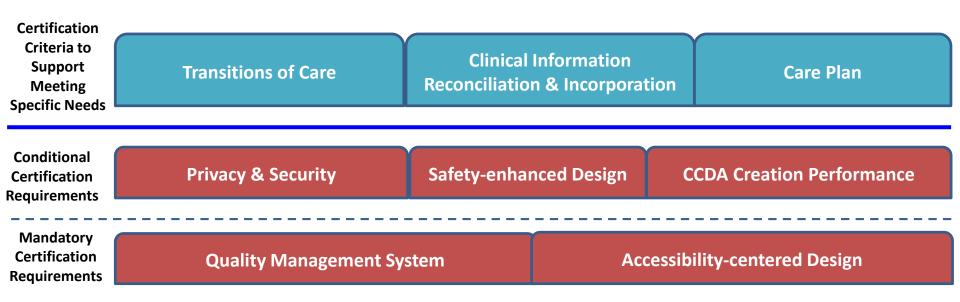
[^] Includes the "QMS" criterion, which may be revised for some health IT developers

^{*} Depends on which family health history criterion is chosen (SNOMED CT or pedigree)

Certified Health IT Module(s) to Support Other Health Care Settings (LTPAC Example)



Long-Term Post-Acute Care Certification (example only)

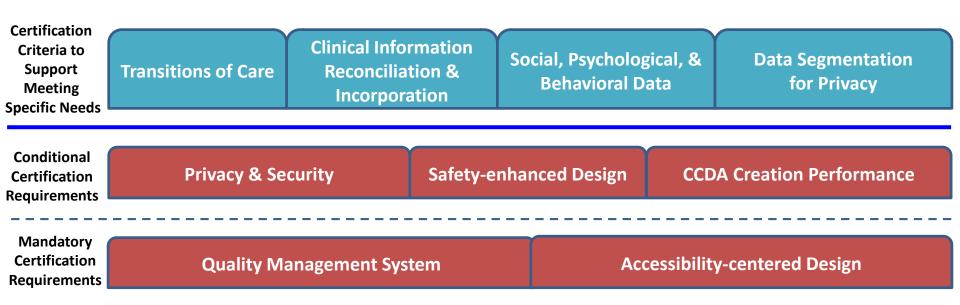


Use of the ONC Health IT Certification Program to Support the Care Continuum

Certified Health IT Module(s) to Support Other Health Care Settings (Behavioral Health Example)



Behavioral Health Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

When and How to Comment



- ONC published the 2015 Edition Proposed Rule in the Federal Register on March 30, 2015
- The comment period is open until May 29, 2015
- You can review the proposed rule and comment here:
 http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0572
- To assist in commenting on the rule, ONC provides a:
 - ☐ Microsoft Word version of the rule

 (http://www.healthit.gov/sites/default/files/2015 editionnprm of disclaimer 3-20-15.docx); and
 - □ Public Comment Template
 (http://www.healthit.gov/sites/default/files/2015editionnprm public comment template 4-1-15 final508 .docx)